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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/757,159

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Barry N. Gellman

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EXAMINER

SHELL, LAURA C

ART UNIT

PAPER NUMBER

3767

MAIL DATE

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07/23/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/757,159	<b>Applicant(s)</b> GELLMAN, BARRY N.	
	<b>Examiner</b> Laura C. Schell	<b>Art Unit</b> 3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 14 May 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 11-20, 22 and 23 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 11-20, 22 and 23 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |                                                                                                            |                                                                                         |
|------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____                                                |

## DETAILED ACTION

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 11 and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Schwartz-Feldman (US Patent No. 5,501,371). Schwartz-Feldman discloses a driving system for use with an injector system (Figs. 1-3 and 7-9), the injector system comprising: a housing (28) defining a lumen (22) and having an output end (near 36) and a driving system connection end (near 52); a needle assembly (84) coupled to the output end of the housing (coupled at 36) for coupling to a needle; and a mixing member (100) extending through the lumen from the driving system connection end to at least the output end (Fig. 1 discloses that the needle assembly connects at 36 and Fig. 1 also discloses that end portion 140a of the mixing member extends into the needle assembly); and the driving system (50; col. 4, lines 12-14 disclose that 50 is the member that does the driving and is therefore the driving system) comprises: a drive mechanism (50); an actuator (56) coupled to the drive mechanism to actuate the drive mechanism (56 are the flanges which the user would grip in order to actuate the drive mechanism 50); and a rotatable interfacing member (interfacing member is made of ribs 66a, 66b, 66c and 66d which are located on the inner surface of 62, since 62 rotates,

Art Unit: 3767

ribs 66a-66d rotate as well and these couple to the notches 110a, 110b, 110c and 110d on the mixing member which cause the mixing member to rotate (col. 3, lines 40-43) coupled to the drive mechanism for coupling the mixing member to rotate the mixing member when the interfacing member is driven by the drive mechanism (col. 3, lines 40-43), wherein the mixing member is rotatable in the needle assembly and the lumen (Fig. 1 discloses that the mixing member 100 rotates within the lumen 22 as well as within the needle assembly, as end portion 140a of the mixing member extends within the needle assembly in Fig. 1, where the end portion of the needle assembly that connects to the housing is at 36).

In reference to claim 17, Schwartz-Feldman discloses that the driving system is capable of coupling to an injector system (Fig. 1), the injector system comprising a tubular member (28) and a mixing member (100) extending through the tubular member (Fig. 1).

Claims 18-20, 22 and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by Hicks (US Patent No. 2,825,134). Hicks discloses a coupling system (Fig. 1) for use with a tube of a syringe (10), comprising: a housing (16) for coupling to the tube of the syringe; a drive mechanism disposed within the housing (34); a mixing member (24) for coupling to the drive mechanism, the mixing member for extending into the tube of the syringe and being rotatable within the tube of the syringe to mix and deliver an injectable from the tube of the syringe; and an actuator (30) coupled to the drive mechanism to actuate the drive mechanism and thereby cause rotation of the

Art Unit: 3767

mixing member (21 couples the drive mechanism (34) to the mixing member (24) and the interfacing member (21) rotates which thus causes the mixing member (24) to rotate as well).

In reference to claim 19, Hicks discloses that the mixing member (24) is coupled to the drive mechanism (coupled to each other via interfacing member 21).

In reference to claim 20, Hicks discloses that the housing further comprises a mating portion (at 16), the mating portion being capable of mating with the tube of the syringe.

In reference to claim 22, Hicks discloses that the tube of the syringe comprises an injectable material (col. 3, lines 39-43).

In reference to claim 23, Hicks discloses that the housing comprises finger grips (40).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

Art Unit: 3767

2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 12-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schwartz-Feldman (US Patent No. 5,501,371) in view of Critchlow et al. (US 2003/0171712). Schwartz-Feldman discloses the device substantially as claimed except for a low torque motor, a battery or a switch. Critchlow, however, discloses a hand-held syringe (Fig. 9) with a high speed, low torque motor (paragraph [0053]), that the motor is coupled to a battery as an energy source (paragraph [0046]) and that the actuator comprises a switch (paragraph [0128]). Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Hicks with the specific motor, energy source and switch, as taught by Critchlow, in order to provide an injector system that is powerful enough to mix and inject such viscous material, as well as be hand-held and portable.

### ***Response to Arguments***

Applicant's arguments with respect to claims 11-20, 22 and 23 have been considered but are moot in view of the new ground(s) of rejection.

The examiner would like to point out that she was not able to find any arguments directed towards independent claim 18 and dependent claims 19, 20, 22 and 23, pertaining to why independent claim 18 was not amended and why it distinguishes itself over the prior art of record. Therefore the examiner is maintaining her previous rejection of claims 18-20, 22 and 23 under Hicks.

**Conclusion**

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura C. Schell whose telephone number is (571) 272-7881. The examiner can normally be reached on Monday-Friday 9am-5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3767

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

LCS

*LCS*

KEVIN C. SIRMONS  
SUPERVISORY PATENT EXAMINER

*Kevin C. Sirmons*